

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

**BOEHRINGER INGELHEIM INTERNATIONAL
GmbH and BOEHRINGER INGELHEIM
PHARMACEUTICAL, INC.,**

Plaintiff,

v.

MYLAN PHARMACEUTICALS INC.,

**Defendant and
Counterclaim Plaintiff.**

Civil Action No.: 05-0854 (KAJ)

**ANSWER, SEPARATE DEFENSES AND COUNTERCLAIMS
OF MYLAN PHARMACEUTICALS INC.**

Mylan Pharmaceuticals Inc. (“Mylan”), by its undersigned attorneys, answers and responds to the Complaint of Boehringer Ingelheim International GmbH (“BII”) and Boehringer Ingelheim Pharmaceutical, Inc. (“BIPI”), collectively referred to as “Plaintiffs”, as follows:

Parties

1. Mylan admits the allegations of paragraph 1.
2. Mylan admits the allegations of paragraph 2.
3. Mylan admits that Mylan is incorporated under the laws of the State of

West Virginia and that it has a principal place of business in Morgantown, West Virginia at the address set forth in paragraph 3. Mylan further admits that the quoted statements set forth in paragraph 3 are excerpts from Mylan's website (www.mylanpharms.com) that states, "Last year, pharmacists filled more than 197 million prescriptions with products

from Mylan, making it the #1 US-based manufacturer of generic pharmaceutical products.” Mylan is without sufficient knowledge or information to form a belief as to the truth of the remaining allegations set out in paragraph 3 and, therefore, denies those allegations.

4. Mylan admits the allegations of paragraph 4.

Jurisdiction and Venue

5. Mylan admits that Plaintiffs purport to allege an action for patent infringement and that this Court has jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

6. Mylan admits the allegations of paragraph 6 for purposes of this litigation.
7. Mylan admits the allegations of paragraph 7.

Background

8. Mylan admits that United States Patent No. 4,886,812 (“the ‘812 patent”), entitled “Tetrahydro-Benzthiazoles, The Preparation thereof and Their Use as Intermediate Products or as Pharmaceuticals” states on its face that it was issued on December 12, 1989 to inventors Gerhart Griss, Claus Schneider, Rudolf Hurnaus, Walter Kobinger, Ludwig Pichler, Rudolf Bauer, Joachim Mierau, Dieter Hinzen and Gunter Schingnitz and assigned to Dr. Karl Thomae GmbH. Mylan denies that the ‘812 patent was duly and legally issued. Mylan is without sufficient knowledge or information to form a belief as to the truth of the remaining allegations set out in paragraph 8 and, therefore, denies those allegations.

9. Mylan admits the allegations of paragraph 9.

10. Mylan admits that the publication *Approved Drug Products with Therapeutic Equivalence Evaluations* (the “Orange Book”) is published by the Food and

Drug Administration (“FDA”), as was established by the Federal Food, Drug, and Cosmetic Act. Mylan admits that the ‘812 patent is listed in the Orange Book. Mylan is without sufficient knowledge or information to form a belief as to the truth of the remaining allegations set out in paragraph 10 and, therefore, denies those allegations.

11. Mylan admits the allegations of paragraph 11.

12. Mylan admits the allegations of paragraph 12.

13. Mylan admits that its letter dated October 26, 2005 stated that the products described in Mylan’s Abbreviated New Drug Application (“ANDA”) would not infringe any valid claim of the ‘812 patent. Mylan further admits that its ANDA included a certification pursuant to 21 U.S.C. § 355(j)(2)(vii)(IV). Mylan denies the remaining allegations of paragraph 13.

Claim for Relief

14. Mylan incorporates its foregoing responses to paragraphs 1-13 as if fully set forth herein.

15. Mylan denies each and every allegation of paragraph 15.

16. Mylan denies each and every allegation of paragraph 16.

17. Mylan denies each and every allegation of paragraph 17.

18. Mylan denies each and every allegation of paragraph 18.

SEPARATE DEFENSES

First Defense – Non-Infringement

Mylan has not infringed and is not infringing, directly or indirectly, any valid claim of the ‘812 patent.

Second Defense – Invalidity

The claims of the '812 patent are invalid for failure to meet one or more of the conditions for patentability specified in Title 35 of the United States Code.

Third Defense – Failure to State a Claim

The Complaint fails to state a claim upon which relief can be granted.

COUNTERCLAIMS

For their counterclaims against Boehringer Ingelheim International GmbH ("BII") and Boehringer Ingelheim Pharmaceutical, Inc. ("BIPI"), collectively referred to as "Plaintiffs," Mylan Pharmaceuticals Inc. ("Mylan") states as follows:

Parties

1. Mylan Pharmaceuticals Inc. is a corporation organized and existing under the laws of the State of West Virginia, having its principal place of business at 781 Chestnut Ridge, Morgantown, West Virginia 26505.

2. Upon information and belief, Boehringer Ingelheim International GmbH ("BII") is a corporation organized and existing under the laws of Germany, having an office and place of business at Binger Strasse 173, 55216 Ingelheim, Germany. Upon information and belief, BII or its corporate predecessors have been the owner of the entire right, title and interest in and to U.S. Patent No. 4,886,812 ("the '812 patent").

3. Upon information and belief, Boehringer Ingelheim Pharmaceutical, Inc. ("BIPI") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 900 Ridgebury Road, Ridgefield, Connecticut 06877. Upon information and belief, BIPI is engaged in the business of marketing prescription pharmaceutical products in the United States.

Jurisdiction and Venue

4. The Court has jurisdiction over the subject matter of these counterclaims under 28 U.S.C. §§ 1331, 1338(a) and 2201.

5. Venue is proper in this District under 28 U.S.C. §§ 1391(c) and 1400 (b).

6. Plaintiffs are subject to personal jurisdiction in this District.

First Counterclaim - Declaratory Judgment of Non-Infringement

7. Paragraphs 1-6 of the Counterclaim are incorporated as if fully set forth herein.

8. Mylan has not infringed and is not infringing, directly or indirectly, any valid claim of the '812 patent.

9. Unless Plaintiffs are enjoined, Mylan believes Plaintiffs will continue to assert that Mylan is infringing valid claims of the '812 patent and will continue to interfere with Mylan's business with respect to its ANDA for pramipexole dihydrochloride tablets and those products it proposes to manufacture, use, offer for sale and sell.

10. Mylan will be irreparably harmed if Plaintiffs are not enjoined from continuing to assert the '812 patent and from interfering with Mylan's business.

11. Mylan is entitled to a declaratory judgment that Mylan has not infringed, directly or indirectly, any valid claim of the '006 patent.

Second Counterclaim - Declaratory Judgment of Invalidity

12. Paragraphs 1-11 of the Counterclaim are incorporated as if fully set forth herein.

13. The claims of the '812 patent are invalid for failure to meet one or more of the conditions for patentability specified in Title 35 of the United States Code.

14. Unless Plaintiffs are enjoined, Mylan believes Plaintiffs will continue to assert that Mylan is infringing valid claims of the '812 patent and will continue to interfere with Mylan's business with respect to its ANDA for pramipexole dihydrochloride tablets and those products it proposes to manufacture, use, offer for sale and sell.

15. Mylan will be irreparably harmed if Plaintiffs are not enjoined from continuing to assert the '812 patent and from interfering with Mylan's business.

16. Mylan is entitled to a declaratory judgment that the claims of the '812 patent are invalid.

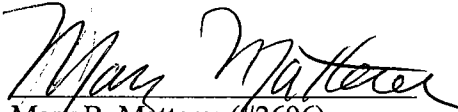
REQUEST FOR RELIEF

WHEREFORE, Mylan respectfully requests that this Court enter judgment:

- a. dismissing the Complaint with prejudice and denying each and every prayer for relief contained therein;
- b. declaring that Mylan has not infringed, directly or indirectly, any valid claim of the '812 patent and/or that the '812 patent is invalid;
- c. enjoining Plaintiffs, their respective officers, employees, agents, representatives, attorneys and others acting on its behalf, from representing to anyone, either directly or indirectly, that Mylan has infringed or is infringing, directly or indirectly, the '812 patent; and
- d. awarding to Mylan any such further relief as this Court may deem necessary, just and proper.

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Dated: January 4, 2006

CERTIFICATE OF SERVICE

I, Mary B. Matterer, hereby certify that on January 4, 2006, I caused to be electronically filed an Answer, separate Defenses and Counterclaims with the Clerk of the Court using CM/ECF, which will send notification of such filings to the following:

Jack B. Blumenfeld, Esquire
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and that I caused copies to be served upon the following in the manner indicated:

BY HAND

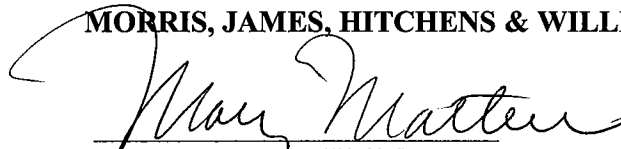
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